

### REMARKS

Favorable reconsideration of this application is respectfully requested in view of the previous amendments and following remarks.

The claimed subject matter at issue here is drawn generally to methods for assembling a blood treatment circuit and a filter unit aseptically connected to a connected bag set in order to assemble a blood treatment circuit. The method of independent Claim 3 involves connecting a bag set and a filter unit. The connected bag set is composed of a primary bag holding collected blood and a plurality of second bags holding blood or blood components. A first tube connects the primary bag to the secondary bags. A third tube connects the secondary bags to one another. The filter unit includes an inlet and an outlet, a filter medium, and a second tube connected to both the inlet and outlet, and to which a bag is not connected. The method comprises cutting either the first or third tube so that either the first or third tube comprises first and second cut ends, and cutting the second tube, such that the second tube comprises first and second cut ends. The method further comprises aseptically connecting the first cut end of the first tube or third tube to the first cut end of the second tube, and connecting the second cut end of the first tube or third tube to the second cut end of the second tube, thereby placing the filter unit along the first tube or third tube.

The method of independent Claim 4 is similar to the above method, but further includes sterilizing the connected bag set and sterilizing the filter unit, wherein a second tube has both ends connected to an inlet and outlet of the filter unit, and to which a bag is not connected.

Independent Claim 20 pertains to a filter unit to be aseptically connected to a connected bag set in order to assemble a blood treatment circuit. This claim, though

it does not recite a method, is largely commensurate in scope with Claim 3 discussed above.

Claims 3, 4, 7, 8, 20, 26-28, 30 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Johnson et al ("Johnson", U.S. Patent No. 5,180,504) in view of Fell (U.S. Patent No. 6,733,433). The Official Action takes the position that Johnson discloses each aspect of the method recited in the claims, with the exception of a plurality of secondary bags, a first tube connecting a primary bag to secondary bags, and a third tube connecting secondary bags to each other. The Official Action relies on the disclosure of Fell to cure these deficiencies, and concludes that it would have been obvious to an ordinarily skilled artisan to combine the references.

Independent Claims 3, 4 and 20 are each amended to provide, *inter alia*, that a filter medium, including an inlet and outlet, removes specific components from fluid introduced through the inlet, and a second tube, "both ends of which are connected to said inlet and outlet, and to which a bag is not connected."

Johnson describes to a system for removing undesired matter from blood cells. Johnson discloses a primary bag or container 16 and a filtration assembly 14. The filtration assembly 14 includes a transfer container 34, a flow path 36, and a filter 40. In an alternative embodiment, tubing 68 connects a sterilization device 66a to the primary bag 16. The filter 40 includes an inlet and outlet through which fluid flows from the primary bag 16 to the transfer bag 34. Johnson further discloses an air vent line 63 that provides an air venting path around the filtration device. In operation, fluid (i.e., blood or components of blood) is stored in the primary bag 16. The primary bag is held above the transfer bag 34, and the fluid is conveyed by gravity through the flow path 36 and filtration device 40 to remove white blood cells.

Column 7, lines 33-43. The air vent line 63 operates to allow for venting of air trapped in the transfer bag. One way valve 67 allows fluid through the air vent line 63 only in a direction away from the transfer bag.

Johnson fails to disclose the second tube as claimed, such that both ends of the second tube are connected to the inlet and outlet and to which a bag is not connected. The Official Action's interpretation of Johnson identifies the air vent 63 as corresponding to the claimed second tube and the tubing 68 as corresponding to the claimed first tube. In the claimed arrangement, a bag is not connected to the second tube, which allows for the possibility to select a position where a filter unit is connected to a connected bag set. In contrast, Johnson's air vent 63 is connected to the transfer bag 34 to vent excess air that may be trapped in the transfer bag, and the position of the filter is fixed relative to the transfer bag. Fell does not cure this deficiency, as Fell pertains to the use of multiple collection bags. Because the combination of Johnson and Fell fails to disclose a second tube connected to the inlet and outlet of a filter, and not connected to a bag, the rejection is improper. Accordingly, allowance of these independent claims and withdrawal of the rejection is respectfully requested.

Additionally, the Official Action relies on Johnson's disclosure of tubing 68 to show the first tube as claimed. It is noted that the tubing 68 is disclosed in an alternative embodiment of Johnson, that is separate from the embodiment relied to show other features. It is not clear from the Official Action whether the embodiment in Fig. 4 of Johnson, which appears to be the primary embodiment relied on by the Official Action, is to be modified in a manner consistent with Johnson's embodiment in Fig. 6, where the tubing 68 is provided.

By this Amendment, Claims 1, 2, 5, 6, 14, 17-19, 21-25 and 31-33 are cancelled. Claims 9, 10, 12, 15 and 16 are amended to correct dependencies in light of the cancellation of the above claims.


The remainder of the claims depend from one of the independent claims addressed above, which are allowable. For at least this reason, these dependent claims are also allowable.

Early and favorable consideration is respectfully requested. In the event that there are any questions concerning this response, or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that the prosecution of the application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By:   
Matthew L. Schneider  
Registration No. 32814

P.O. Box 1404  
Alexandria, VA 22313-1404  
703 836 6620